DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

#19

MAY 8 1991

Re: Altace
Docket No. 91E-0136

The Honorable Harry F. Manbeck, Jr.
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Mr. Manbeck:

This is in regard to the application for patent extension for U.S. Patent No. 4,587,258, filed by Hoechst-Roussel Pharmaceuticals, Inc., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Altace, the human drug product claimed by the patent.

The total length of the review period for Altace is 2,551 days. Of this time, 1,738 days occurred during the testing phase and 813 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 5, 1984.

   The applicant claims January 27, 1984, as the date the investigational new drug application (IND) for Altace became effective. However, FDA records indicate that the IND became effective on February 5, 1984.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: November 7, 1988.

   The applicant claims November 2, 1988, as the date the new drug application for Altace (NDA 19-901) was initially submitted. However, FDA records indicate that the application was received on November 7, 1988.

3. The date the application was approved: January 28, 1991.

   FDA has verified the applicant's claim that NDA 19-901 was approved on January 28, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Tatsuya Ikeda
Patent Department
Hoechst Celanese Corporation
P.O. Box 2500
Route # 202-206 North
Somerville, New Jersey 08876-1258